



Practitioner's Docket No. IB-1627

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Antoni P. Tomsia

Application No.: 09/845,597

Filed: 04/30/2001

For: Glass/Ceramic Coatings for Implants

Group No.: 1775

Examiner: Sperty

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF  
(PATENT APPLICATION-37 C.F.R. § 1.192)

1. Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on June 22, 2004.
2. STATUS OF APPLICANT

This application is on behalf of a small entity. A statement was already filed.

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CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\*

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Stephanie Blackmon  
Signature

Date: 2/22/05

Stephanie Blackmon  
(type or print name of person certifying)

\* Only the date of filing ('1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under '1.8 continues to be taken into account in determining timeliness. See '1.703(f). Consider "Express Mail Post Office to Addressee" ('1.10) or facsimile transmission ('1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

### 3. FEE FOR FILING APPEAL BRIEF

Pursuant to 37 C.F.R. § 1.17(c), the fee for filing the Appeal Brief is:

small entity \$250.00

**Appeal Brief fee due \$250.00**

### 4. EXTENSION OF TERM

The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

Applicant petitions for an extension of time under 37 C.F.R. § 1.136 (fees: 37 C.F.R. § 1.17(a)(1)-(5)) for five months:

Fee: \$1,080.00

An additional extension of time of one month is required and a petition under 37 C.F.R. 1.136(b) is attached hereto, along with the appropriate fee.

### 5. TOTAL FEE DUE

The total fee due is:

Appeal brief fee	\$250.00
Extension fee (if any)	\$1,080.00

**TOTAL FEE DUE \$1,330.00**

### 6. FEE PAYMENT

Authorization is hereby made to charge the amount of \$1,330.00 to Deposit Account No. 12-0690.

A duplicate of this transmittal is attached.

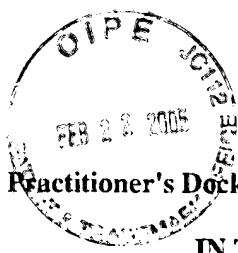
### 7. FEE DEFICIENCY

If any additional extension and/or fee is required, and if any additional fee for claims is required, charge Deposit Account No. 12-0690.

Date: 2/22/2005

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Practitioner's Docket No. IB-1627

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Antoni P. Tomsia

Application No.: 09/845,597

Group No.: 1775

Filed: April 30, 2001

Examiner: Sperty

For: Glass/Ceramic Coatings for Implants

Commissioner for Patents  
Washington, D.C. 20231

**ATTENTION: Board of Patent Appeals and Interferences**

**APPELLANT'S BRIEF (37 C.F.R. § 1.192)**

This brief is in furtherance of the Notice of Appeal, filed in this case on June 22, 2004.

The fees required under § 1.17, and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying **TRANSMITTAL OF APPEAL BRIEF**.

This brief is transmitted in triplicate. (37 C.F.R. § 1.192(a))

This brief contains these items under the following headings, and in the order set forth below (37 C.F.R. § 1.192(c)):

- I      REAL PARTY INTEREST
- II     RELATED APPEALS AND INTERFERENCES
- III    STATUS OF CLAIMS
- IV    STATUS OF AMENDMENTS
- V    SUMMARY OF INVENTION
- VI    ISSUES
- VII   GROUPING OF CLAIMS
- VIII   ARGUMENTS
  - ARGUMENT: VIIIA   REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH
  - ARGUMENT: VIIIB   REJECTIONS UNDER 35 U.S.C. § 102
  - ARGUMENT: VIIIC   REJECTIONS UNDER 35 U.S.C. § 103
  - ARGUMENT: VIIID   REJECTIONS OTHER THAN 35 U.S.C. § 102, 103 AND 112
- IX   APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

The final page of this brief bears the practitioner's signature.

## **I REAL PARTIES IN INTEREST (37 C.F.R. § 1.192(c)(1))**

The real party in interest in this appeal is the following party: The Regents of the University of California

**II RELATED APPEALS AND INTERFERENCES**  
**(37 C.F.R. § 1.192(c)(2))**

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal there are no such appeals or interferences.

### **III STATUS OF CLAIMS (37 C.F.R. § 1.192(c)(3))**

#### **A. TOTAL NUMBER OF CLAIMS IN APPLICATION**

Claims in the application are: 1-30

#### **B. STATUS OF ALL THE CLAIMS IN APPLICATION**

1. Claims canceled: 2, 4, 6-7, 13-19 and 29.
2. Claims withdrawn from consideration but not canceled: none
3. Claims pending: 1, 3, 5, 8-12, 20-28, 30
4. Claims allowed: none
5. Claims rejected: 1, 3, 5, 8-12, 20-28 and 30

#### **C. CLAIMS ON APPEAL**

The claims on appeal are: 1, 3, 5, 8-12, 20-28 and 30.

#### **IV STATUS OF AMENDMENTS (37 C.F.R. § 1.192(c)(4))**

There are no non-entered amendments after final rejection.

## **V SUMMARY OF INVENTION (37 C.F.R. § 1.192(c)(5))**

In one embodiment the invention described in the present application is a multilayer article having a metal substrate and a first layer having a glass composition, where the glass composition may be made of about 44.2 to 67.7 wt % SiO<sub>2</sub>, 10.1 to 23.4 wt % CaO, 5.7 to 13.3 wt % MgO, 10.3 to 23.6 wt % Na<sub>2</sub>O, 2.2 to 6.5 wt % K<sub>2</sub>O and 6.0 wt % P<sub>2</sub>O<sub>5</sub> (similar to claim 1, this composition is supported on page 7, lines 20-22 of U.S. Serial No. 09/845,597 and page 9, Table I, where the SiO<sub>2</sub> ranges between 44.2 and 67.7 wt% in column 1 of Table 1, and Na<sub>2</sub>O content ranges between 10.3 and 23.6 wt % in column 2 of Table 1, and the K<sub>2</sub>O content ranges between 2.2 and 6.5 wt% in column 3 of Table 1, and CaO ranges between 10.1 and 23.4 wt %, see column 4 of Table 1, and MgO ranges between 5.7 and 13.3 wt% in column 5 of Table 1 and P<sub>2</sub>O<sub>5</sub> is 6.0 %, column 6, Table 1. The glass composition is also supported in the provisional application U.S. Serial No. 60/204,556 at page 2, Table I). The glass composition contains hydroxyapatite particles in an amount up to 50 wt %, (this recitation is supported in 09/845,597 at page 12, line 9 and in the provisional application 60/204,556 at page 12, abstract, lines 4-6, page 18, col. 1, last 4 lines which recite “the glasses can be used alone or mixed with HA” (HA = hydroxyapatite)). The article is multilayered (claims 3, 5) and has multiple layers having gradient compositions (claim 5, support for multilayer and gradient compositions is found in 09/845,597 at page 12, line 13 and in 60/204,556 on page 7, col. 1 which recites “multilayered coatings were fabricated” and “the goal was to achieve a gradient in composition”, see the penultimate line of page 7, col. 1) First, second and intermediate layers are disclosed, for example see Table II, page 14 of the provisional application 60/204,556 which recites in the column titled “glass layers” two and three layered glass articles.

Layers having specific glass compositions such as the first layer having about 54.5 wt % SiO<sub>2</sub>, about 15 wt % CaO, about 8.5 wt % MgO, about 12.0 wt % Na<sub>2</sub>O, about 4.0 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>, and the glass composition in the first intermediate layer comprises about 61.1 wt % SiO<sub>2</sub>, about 12.6 wt % CaO, about 7.2 wt % MgO, about 10.3 wt % Na<sub>2</sub>O, about 2.8 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>, and the substrate is Ti or Ti6Al4V, see claims 8 and 9. Support for Ti or Ti6Al4V substrate is found in the specification at page 6, line 13 and in the provisional application 60/204,556 at page 2, line 4. Support for the specific composition is found in the specification 09/845,597 at Table I, (6P55 corresponds to 54.5 wt % SiO<sub>2</sub>, about 15 wt % CaO, about 8.5 wt % MgO, about 12.0 wt % Na<sub>2</sub>O, about 4.0 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub> and 6P11 corresponds to 61.1 wt % SiO<sub>2</sub>, about 12.6 wt % CaO, about 7.2 wt % MgO, about 10.3 wt % Na<sub>2</sub>O, about 2.8 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>) and Table II of 09/845,597 which recites the “glass layers” as ---sub/6P61/6P55---, which corresponds exactly to that claimed. Support for this recitation is also found in the provisional specification 60/204,556 as filed at Table I on page 2 (identical to Table I in the 09/845,597 application) and Table II on page 14 of 60/204,556.

Other embodiments of the present invention include other specific layers having specific compositions such as a first layer comprises about (claim 10) 52.7 wt% SiO<sub>2</sub>, about 12.6 wt % CaO, about 7.1 wt % MgO, about 17.0 wt % Na<sub>2</sub>O, about 4.6 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>, and the glass composition in the first intermediate layer comprises about 56.5 wt % SiO<sub>2</sub>, about 15 wt % CaO, about 8.5 wt % MgO, about 11.0 wt % Na<sub>2</sub>O, about 3.0 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>, and the substrate is Ti or Ti6Al4V. Support for these limitations are found in the 09/845,597 application at Table I on page 9 ( note 6P53-a of Table I corresponds to 52.7 wt% SiO<sub>2</sub>, about 12.6 wt % CaO, about 7.1 wt % MgO, about 17.0 wt % Na<sub>2</sub>O, about 4.6 wt %

K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub> and 6P57 of Table I corresponds to 56.5 wt % SiO<sub>2</sub>, about 15 wt % CaO, about 8.5 wt % MgO, about 11.0 wt % Na<sub>2</sub>O, about 3.0 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>) and support for the different layers in compositions is found at Table III of 09/845,597, page 15. Support for these limitations are also found in the provisional application as filed 60/204,556 at Table I on page 2 and Table II on page 14.

Other embodiments (claim 11) have different compositions of glasses in the different layers, such as one embodiment that has the first layer and first intermediate layer with about 56.5 wt % SiO<sub>2</sub>, about 15 wt % CaO, about 8.5 wt % MgO, about 11.0 wt % Na<sub>2</sub>O, about 3.0 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub> and the hydroxyapatite amount in the first layer is 50 wt%, and the substrate is Ti or Ti6Al4V. Support for this embodiment is found in the specification 09/845,597 in Table I, page 9 and page 15 Table III which recites sub/6P57/(6P57 +HA). Support for this is found in the provisional application as filed at Table I, page 2 and Table II on page 14.

In other embodiments, (claim 12) the first layer and first and second intermediate layers all have the same composition of glass, but has different amounts of hydroxyapatite (HA) in the glass. For example the first layer, the first intermediate layer and the second intermediate layer each comprise about 61.1 wt % SiO<sub>2</sub>, about 12.6 wt % CaO, about 7.2 wt % MgO, about 10.3 wt % Na<sub>2</sub>O, about 2.8 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub> and the hydroxyapatite amount in the first layer comprises 50 wt % and the substrate is Ti or Ti6Al4V. This embodiment is supported in the provisional application 60/204,556 at page 2, column 2 which recites “ multilayered coatings were manufactured by depositing two or three different glass layers on the metal substrates using the previously described method”... “in these coatings the final layer was a composite of glass and HA (50:50 wt %).

In another embodiment (claim 20) there is recited a multilayer article having “n” layers each having a composition as disclosed and supported in claim 1, and containing hydroxyapatite particles. Support for this embodiment is found in the specification as filed at page 10, first full paragraph and in the provisional 60/204,556. Because the provisional discloses “multilayered coatings” on page 2, col. 2, line 29 and page 13, penultimate line, and elsewhere throughout the specification, “n” layers are supported under *In re Kaslow* since the disclosure in the provisional of “multilayered” coatings reasonably conveys to the artisan the inventor had possession of “n” number of coatings.

In another embodiment, claims 21 and 23, the SiO<sub>2</sub> content of the glass composition is limited to between about 53-57 wt %. Support for this limitation is found in the present specification as filed and in the provisional application on page 16, lines 7-8, (which recite “silica content... 57 to 53 wt %).

In another embodiment, claims 25 and 27, the SiO<sub>2</sub> content of the glass composition is limited to between about 56-67.7 wt %. Support for this limitation is found in the present specification as filed and in the provisional application on page 4, col. 2, last 4 lines which teach the silica content being higher than “≈55 wt %”, and Table I which recites an upper limit of SiO<sub>2</sub> content being 67.7 wt %.

In another embodiment, claim 30, there is disclosed a multilayered article where the SiO<sub>2</sub> content is lowest in the first or outer layer. Support for this limitation is found in the specification as filed and in the provisional application 60/204,556 at page 7, col. 2, lines 1-2 where it is recited “the mechanical stability of coatings whose external layer will have a lower SiO<sub>2</sub> content.”

## VI ISSUES (37 C.F.R. § 1.192(c)(6))

- 1) Whether the pending claims are supported by the provisional application 60/204,556, filed May 1, 2000 and thus whether the priority claim made in the Utility application 09/845,597 to 60/204,556 is a valid priority claim.
- 2) Whether claims 1, 8 and 23 are unpatentable under 35 U.S.C. 102(b) as being anticipated by the article titled “HA-bioactive glass composites: High temperature reactivity and ‘in-vitro’ behavior” by Pazo, et al.
- 3) Whether claims 1, 3, 5, 8-12 and 20-28 are unpatentable under 35 U.S.C. 102(b) as being anticipated by “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000. This issue will turn on the priority issue stated above in “1”. Since the priority claim is proper as claimed, the current claims have priority back to May 1, 2000 and this rejection is thus invalid.
- 4) Whether claims 1, 8 and 23 are unpatentable under 35 U.S.C. 102(b) as being anticipated by “Silicate glass coatings on Ti-based implants,” by Pazo et al. This issue will turn on the priority issue stated above in “1”. Since the priority claim is proper as claimed, the current claims have priority back to May 1, 2000 and this rejection is thus invalid.
- 5) Whether claim 30 is unpatentable under 35 U.S.C. 103(a) as being obvious over “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al, published February 2000 in view of “A multilayer approach to fabricate bioactive glass coatings on Ti alloys,” by Gomez-Vega et al, published 1999. This issue will turn on the priority issue stated above in “1”. Since the priority claim is proper as claimed, the current claims have priority back to May 1, 2000 and this rejection is thus invalid.

## VII GROUPING OF CLAIMS (37 C.F.R. § 1.192(c)(7))

The claims appealed herein do not stand or fall together for the following reasons.

Claims 1, 3, 5 and 8 stand or fall together as being patentably distinct because the claims require a specific glass composition and hydroxyapatite concentration.

Claim 9 stands or falls alone because the claim requires a specific combination of glass compositions in the first layer and first intermediate layer and the low SiO<sub>2</sub> content of the glass composition in the first layer is beneficial to the resultant multilayer article.

Claim 10 stands or falls alone because the claim requires a specific combination of glass compositions in the first layer and first intermediate layer and the low SiO<sub>2</sub> content of the glass composition in the first layer is beneficial to the resultant multilayer article.

Claim 11 stands or falls alone because the claim requires a specific glass composition having a specific amount of Hydroxyapatite particles therein and this is disclosed as beneficial in the specification.

Claim 12 stands or falls alone because the claim requires the same glass composition for all layers and a specific glass/hydroxyapatite amount.

Claims 20-28 stand or fall together because the claims require a “n” amount of layers and further teach specific SiO<sub>2</sub> contents that are disclosed as beneficial.

Claim 30 stands or falls alone because the claim recites a multilayer having in the first layer a SiO<sub>2</sub> content that is lower in the other layers, and this low SiO<sub>2</sub> content in the first layer is disclosed in the specification as beneficial.

**VIIIA ARGUMENTS—REJECTIONS UNDER 35 U.S.C. § 112,**

**FIRST PARAGRAPH (37 C.F.R. § 1.192(c)(8)(i))**

The office action has Appellant's claim for priority to Provisional Application 60/201,556 allegedly because the provisional application 60/201,556 does not comply with 35 U.S.C. 112, first paragraph. In response Appellant's respectfully traverse this position and urge that the present application is fully supported and is due priority to the provisional patent application 60/201,556 for the following reasons.

The Office Action (paper no. 11, mailed 2/28/2003, paragraph no. 1, denies Applicant's claim for priority to Provisional Application 60/201,556, because allegedly "the provisional application does not provide a specification disclosing the claimed invention, therefore there is no support for the claimed invention."

The standard for a provisional patent application can be found in MPEP 601 which states that 35 U.S.C. 111(b) mandates the contents of a provisional application specification. 35 U.S.C. 111(b) mandates that a provisional application shall comply with the first paragraph of 35 U.S.C. 112 and include a drawing if necessary. A claim is not required. Applicants respectfully assert that the provisional application as filed does provide support for the invention as currently claimed. Complete support for each and every limitation of Appellant's claims are set forth in this Brief in the "Summary of the Invention" section. Detailed support is found in the provisional application. The provisional application is a compilation of six different peer-reviewed publications all listing some of the current inventors as authors. Appellant's invention was exciting to the scientific community and received wide notice and publications. Those publications serve the content of the provisional application.

The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that

time of the later claimed subject matter, *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983). Precisely how close the original description must come to comply with the description requirement of 35 U.S.C. § 112 must be determined on a case-by-case basis. *In re Wilder*, 736 F.2d 1366, 1375, 222 USPQ 369, 372 (Fed. Cir. 1984). There is no per se rule that ranges in claims added in a continuation application must correspond exactly with those disclosed in the parent application. *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 USPQ 177 (Fed. Cir. 1985). Accordingly, under *Ralston* it is Appellant's position that the repeated mention in the provisional application of the glass composition and where and in what layer a specific composition is deposited are adequate support to so claim in the Utility application.

In arguments in the Final Rejection, the office action appears to be arguing (page 6, last paragraph, paper mailed 02/24/2004) that present claim 1 requires that hydroxyapatite not be present in the glass composition because of the claim language, "wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt %" and "it is the position of the examiner that "up to" includes zero so the HA particles are optional". The Office action is in error here. The word "optionally" has been deleted from the claims so that the claims clearly require hydroxyapatite particles "in an amount up to 50 wt %".

In the final rejection, the office action asserts (page 6, last line to page 7, line 2, paper mailed 02/24/2004) that "priority is denied", in reference to Pazo et al. "HA-bioactive glass composites: High temperature reactivity and "in-vitro" behavior", *Scripta Materialia*, Vol. 34, No. 11, pp. 1729-1733, 1996. No priority is sought to this reference.

In response to Appellant's arguments that there is support in the provisional, and specific passages where Appellant has pointed to support, the final rejection argues (paper mailed

2/24/2004, page 6, lines 10-14) that Appellant's arguments fail because "those passages are from different unconnected documents." This argument is in error and must fail. The "passages" are not from "different, unconnected documents" as the final rejection urges. The alleged "unconnected" documents are connected by the following: 1) they are all part of the provisional application and 2) they all have inventor Tomsia and Saiz on them as co-authors and 3) they all talk about the same subject, that is the present claims. To say, as the final rejection urges, that the documents are simply "unconnected" is an oversimplification. Further, it ignores the standard under the law, and that is what would a reasonable artisan gleam from the provisional application. As set forth in the Summary, the reasonable artisan would readily see that the current inventors are in possession of the claimed subject matter.

**VIIIB ARGUMENTS--REJECTIONS UNDER 35 U.S.C. § 102**  
(37 C.F.R. § 1.192(c)(8)(iii))

Claims 1, 8 and 23 have been rejected as allegedly being anticipated by Pazo et al., "HA-bioactive glass composites: High temperature reactivity and "in-vitro" behavior", *Scripta Materialia*, Vol. 34, No. 11, pp. 1729-1733, 1996. Appellant's respectfully traverse this rejection.

The rejection states that Pazo et al. disclose a multilayered article comprising a Ti or Ti alloy substrate, and the Office Action points to the text of page 1733 and Figures 6 and 7. This characterization of Pazo et al. is in error. Appellant's urge that Pazo et al. does not disclose a multilayered article as required by Appellant's claims. Pazo et al. discloses a glass composition (BAG) that provides both high bioactivity and excellent adhesion to Ti and Ti alloys. The entire purpose of the article is to study the high temperature reactivity between HA and the glass, see pp. 1729, first sentence, last paragraph. The *composite article* being relied on by the Office Action to anticipate Appellant's claims is not a composite of layers, i.e. a "multilayer article having a substrate as required by Appellant's claims", but the mixture of glass and HA, see pp. 1731, paragraph 2, line 4. Figures 6 and 7 of Pazo et al. do not show multilayered articles in accordance with Appellant's invention as the Office Action alleges, but show the surfaces of both samples (which are BAG +HA mixture) after soaking in SBF for different times. Because the reference does not disclose each and every limitation of Applicant's claims, the rejection is in error, and withdrawal is requested.

The final rejection argues that the "references teaches the layering of the claimed glass composition on a metal alloy" and relies on the disclosure as follows for support, ""excellent adhesion to Ti and Ti alloys (5). This disclosure is insufficient support to sustain a 35 U.S.C. 102(b) rejection for a "metal substrate" having layered thereon Appellant's specific glass/hydroxyapatite composition. Each and every limitation must be either explicitly present or

inherent in the prior art reference to sustain a 35 U.S.C. 102(b) rejection. There is no disclosure of a “multi-layer” article where the substrate is comprised of Ti. The final rejection has “invented” a multilayer article and ascribed Ti and Ti alloys as the substrate, but there is not support in Pazo et al. for such contentions.

Accordingly withdrawal of the rejection is respectfully requested.

Claims 1, 8 and 23 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by “Silicate glass coatings on Ti-based implants,” by Pazo et al. This article is not prior art against the present claims because the priority date to which Appellants are entitled is May 1, 2000. Thus this article is not anticipatory under 35 U.S.C. 102(b). Accordingly, withdrawal of the rejection is respectfully requested.

**VIIC ARGUMENTS—REJECTIONS UNDER 35 U.S.C. § 103**

**(37 C.F.R. § 1.192(c)(8)(iv))**

Claims 30 stands rejected under 35 U.S.C. 103(a) as allegedly being obvious over “Glass-hydroxyapatite coatings on titanium-based implants” by Gomez-Vega et al. published February 2000. This article is not prior art against the present claims because the priority date to which Appellants are entitled is May 1, 2000. Thus this article cannot serve as prior art under 35 U.S.C. 103(a). Withdrawal of the rejection is respectfully requested.

**IX APPENDIX OF CLAIMS (37 C.F.R. § 1.192(c)(9))**

1. A multilayer article comprising,  
a metal substrate,  
a first layer comprising an inner and outer surface,  
said first layer comprising a glass composition,  
said glass composition comprising,  
44.2 to 67.7 wt % SiO<sub>2</sub>, 10.1 to 23.4 wt % CaO, 5.7 to 13.3 wt % MgO, 10.3 to 23.6 wt % Na<sub>2</sub>O, 2.2 to 6.5 wt % K<sub>2</sub>O and 6.0 wt % P<sub>2</sub>O<sub>5</sub>,  
wherein said glass composition contains hydroxyapatite particles in an amount of up to 50 wt%.
3. The multilayer article of claim 1,  
wherein there is a first intermediate layer having an inner and outer surface,  
and said first intermediate layer is located between the substrate and first layer,  
said first intermediate layer comprising a glass composition as defined in claim 1.
5. The multilayer article of claim 3,  
wherein there is a second intermediate layer located between the first intermediate layer and the substrate,  
said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,  
wherein the hydroxyapatite concentration is highest in the first layer, lowest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.

8. The multilayer article of claim 1,

wherein the substrate is Ti or Ti6Al4V.

9. The multilayer article of claim 3,

wherein the glass composition in the first layer comprises about 54.5 wt % SiO<sub>2</sub>, about 15 wt % CaO, about 8.5 wt % MgO, about 12.0 wt % Na<sub>2</sub>O, about 4.0 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>,

and the glass composition in the first intermediate layer comprises about 61.1 wt % SiO<sub>2</sub>, about 12.6 wt % CaO, about 7.2 wt % MgO, about 10.3 wt % Na<sub>2</sub>O, about 2.8 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>,

and the substrate is Ti or Ti6Al4V.

10. The multilayer article of claim 3,

wherein the glass composition in the first layer comprises about 52.7 wt% SiO<sub>2</sub>, about 12.6 wt % CaO, about 7.1 wt % MgO, about 17.0 wt % Na<sub>2</sub>O, about 4.6 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>,

and the glass composition in the first intermediate layer comprises:

about 56.5 wt % SiO<sub>2</sub>, about 15 wt % CaO, about 8.5 wt % MgO, about 11.0 wt % Na<sub>2</sub>O, about 3.0 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>,

and the substrate is Ti or Ti6Al4V.

11. The multilayer article of claim 3,

wherein the glass composition in the first layer and the first intermediate layer comprise about 56.5 wt % SiO<sub>2</sub>, about 15 wt % CaO, about 8.5 wt % MgO, about 11.0 wt %

Na<sub>2</sub>O, about 3.0 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub> and the hydroxyapatite amount in the first layer is 50 wt %, and the substrate is Ti or Ti6Al4V.

12. The multilayer article of claim 5,

wherein the glass composition in the first layer, the first intermediate layer and the second intermediate layer each comprise about 61.1 wt % SiO<sub>2</sub>, about 12.6 wt % CaO, about 7.2 wt % MgO, about 10.3 wt % Na<sub>2</sub>O, about 2.8 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub> and the hydroxyapatite amount in the first layer comprises 50 wt % and the substrate is Ti or Ti6Al4V.

20. A multilayer article comprising,

a metal substrate comprising Ti or Ti6Al4V,  
n intermediate layers, where n is an integer,  
a first layer comprising an inner and outer surface,  
said n intermediate layers disposed between the metal substrate and the first layer,  
wherein the n intermediate layers and the first layer each independently comprise a glass/hydroxyapatite admixture comprising a glass composition and hydroxyapatite particles (HA),  
said glass composition comprising,  
about 44.2 to about 67.7 wt % SiO<sub>2</sub>, about 10.1 to about 23.4 wt % CaO, about 5.7 to about 13.3 wt % MgO, about 10.3 to about 23.6 wt % Na<sub>2</sub>O, about 2.2 to about 6.5 wt % K<sub>2</sub>O and about 6.0 wt % P<sub>2</sub>O<sub>5</sub>,

and wherein said hydroxyapatite particles being present in the glass/hydroxyapatite admixture in an amount of up to 50 wt%.

21. The multilayer article of claim 20, wherein:

the first layer has a glass composition which has a SiO<sub>2</sub> content between about 53 to about 57 wt %.

22. The multilayer article of claim 21, wherein:

n=2.

23. The multilayer article of claim 1, wherein:

the first layer has a glass composition which has a SiO<sub>2</sub> content between about 53 to about 57 wt %.

24. The multilayer article of claim 23, wherein:

n=2.

25. The multilayer article of claim 20, wherein:

the first layer has a glass composition which has a SiO<sub>2</sub> content between about 56 to about 67.7 wt %.

26. The multilayer article of claim 25, wherein:

n=2.

27. The multilayer article of claim 1, wherein:

the first layer has a glass composition which has a SiO<sub>2</sub> content between about 56 to about 67.7 wt %.

28. The multilayer article of claim 27, wherein:

n=2.

30. The multilayer article of claim 3,

wherein there is a second intermediate layer located between the first intermediate layer and the substrate,

said first layer, first intermediate layer and said second intermediate layer all comprising a glass composition as defined in claim 1,

wherein the  $\text{SiO}_2$  concentration is lowest in the first layer, highest in the second intermediate layer, and present in the first intermediate layer in an amount that is in between the first layer and the second intermediate layer.

Respectfully Submitted,

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